

**Response to Office Action**  
**Gholam-Reza Zadno-Azizi, *et al.***  
**U.S.S.N. 10/081,569**

## **EXHIBIT 1**

**Continuation of Invention Disclosure of**

**Title: Flow Control Device**

**Drawing Attached: Reza Zadno**

**Description of Drawing:**

The Flow Control Device valve consists of two distinct parts; a metallic member formed from a shapable alloy such as NiTi or stainless steel, and a flexible member formed from a material such as silicone or latex rubber.

The two members are joined by using conventional means. They can be laminated together using adhesive bonding or mechanically joined using an insert molding technique.

The alloy member having spring like qualities is formed from a larger diameter that can be compressed to fit in the respective vasculature or channel after it is deployed. The compression force allows the device to securely fit inside the wall of the vasculature.

The valve section is configured in such a fashion as to open at appropriate cracking pressures. In other words, when the cracking pressure threshold is exceeded, the valve will allow fluid passage. When the pressure drops below the threshold, the valve closes, discontinuing fluid flow. Since the fluid flow is always uni-directional the valve cracking pressure is set for the specific application.

The valve is designed to crack at pressures in the range of 0.2 psi (14cm of H<sub>2</sub>O) to 3.0 psi (211 cm H<sub>2</sub>O) for the urinary incontinence application.

For the venous application the valve is designed to crack or permit fluid flow at pressures ranging from 0.005 psi (0.3 mmHg) to 1.00 psi (52 mmHg).

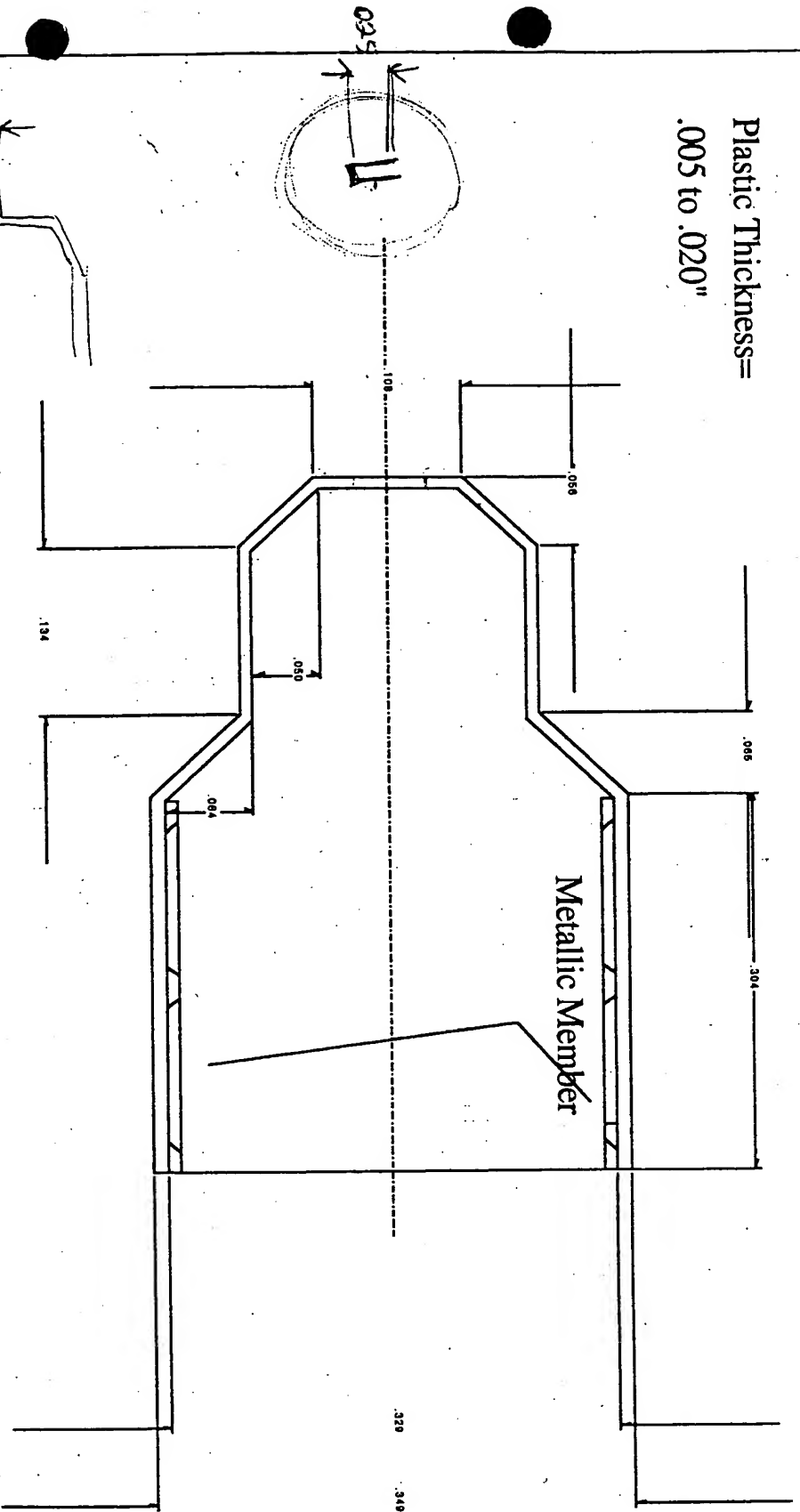
An optional material for the polymeric flexible member could be a shape memory alloy such as NiTi or other iron based shape memory alloys.

These device materials are of biocompatible composition and easily sterilized by conventional means such as with ethylene oxide or gamma radiation sterilization methods.

*APM Kavanagh Zed*

Metallic Member Thickness=.005 to .015"

Plastic Thickness=.005 to .020"



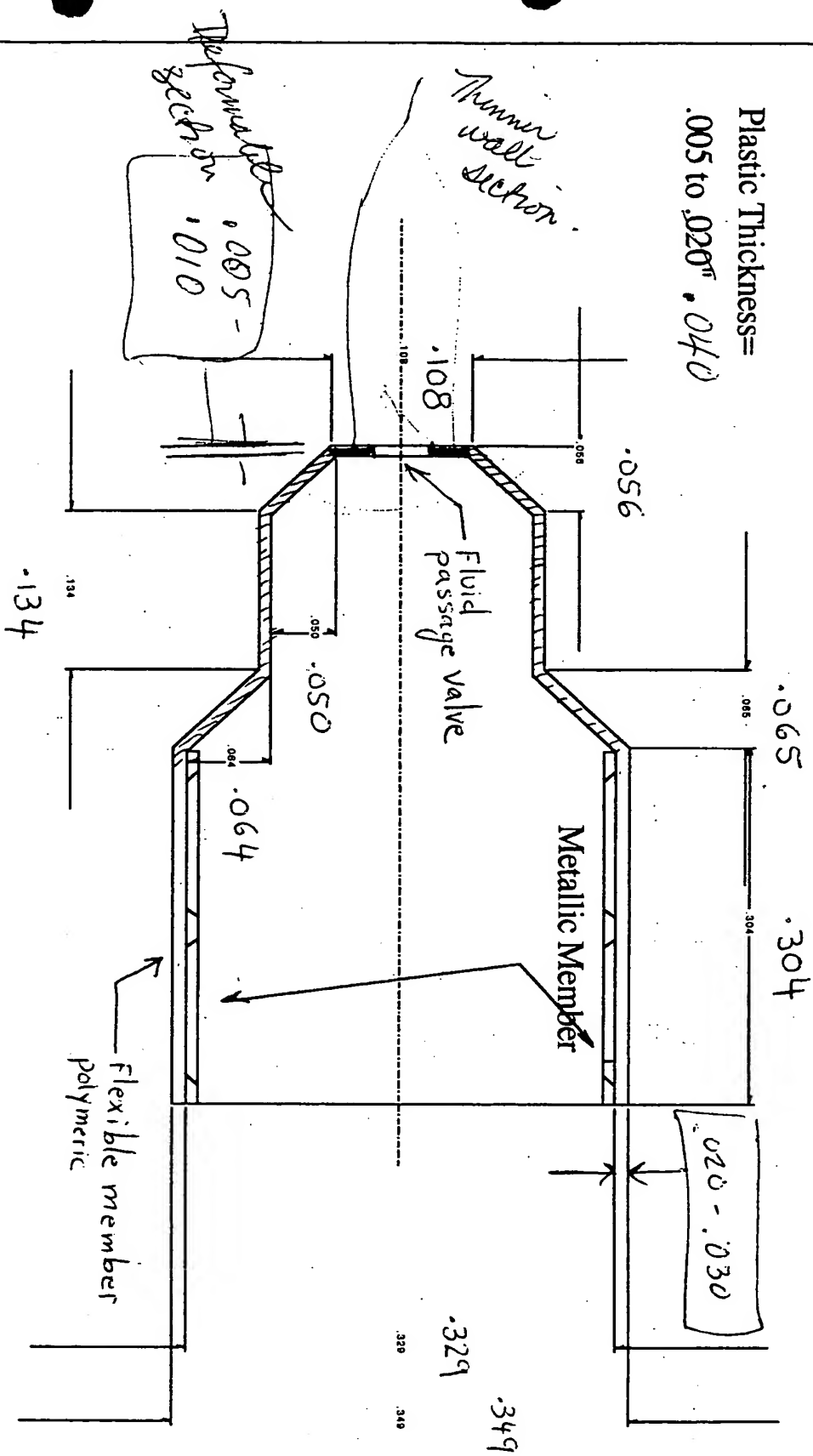
Confidential

pressure valve slit design

Title: Flow Control Valve	
Materials:	Name: Reza Zadno
SS, Nitinol + Elastomeric Polymers	Date:

Metallic Member Thickness=.005 to .015"

Plastic Thickness=.005 to .020", .040



**Confidential**

Title: Flow Control Valve	
Materials: SS, Nitinol + Elastomeric Polymers	Name: Reza Zadno
	Date: